

Application No. 10/804,761

REMARKS

Claims 22, 28-34 and 79 are pending. By this Amendment, Applicants request that claims 36 and 27 be withdrawn in conformity with the response to the restriction requirement filed on April 3, 2006.

Claim Objections

Claims 36 and 37 were objected to as depending from a withdrawn claim. Applicants request that claims 36 and 27 be withdrawn in conformity with the response to the restriction requirement filed on April 3, 2006.

Claim Rejections

Claims 22, 28-34 and 79 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,549,679 to Kuslich in view of 6,413,536 to Gibson. This rejection is respectfully traversed. The '679 patent is directed to the use of a container in the intervertebral disc space. Claims 22, 28-34 and 79 are directed to a method of treating a vertebral bone using a container and as such are patentably distinct from the container in the '679 Patent used to treat intervertebral disc degeneration. Although the Examiner states that this argument and the Board decision in Hochschuler v. Kuslich are not persuasive, Applicants respectfully disagree.

As stated in the Official Gazette of January 2007, there are three categories of Board Decisions: precedential, informative and routine. Precedential opinions are binding law. Informative and routine opinions may be cited for whatever persuasive value they have. Here, the decision in Hochschuler v. Kuslich is incredibly persuasive. In, Hochschuler v. Kuslich the exact same fact scenario and legal issue was presented to the Board, that is, whether the use of a container in the intervertebral disc space is patentably distinct from the use of a container in the vertebral bone. The Board, the USPTO's appellate body, ruled that there is a patentable distinction. Thus, the opinion in Hochschuler v. Kuslich is very persuasive in that the very same prior art, the Kuslich '679 patent, was considered by the Board and the Board determined that the

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subject matter of claims directed to a vertebral bone are patentably distinct from the '679 patent. Applicants cannot comprehend why an opinion by the Board, the USPTO's appellate body, on the exact same issue at hand is not persuasive to this Examiner.

Although the Examiner refuses to consider an opinion on the issue by the Board, the Examiner will consider arguments based on his own misunderstanding of human anatomy. The Examiner argues that the, "entire spinal cord can be considered a vertebral body." This is absolutely contrary to the actual anatomy of the human body. The spinal cord is a column of nerve tissue that runs from the base of the skull down the back. The vertebral bones surround and protect the spinal cord. In no way can the entire spinal cord be considered a vertebral body.

"Each **vertebra** consists of two essential parts—an anterior solid segment or *body*, and a posterior segment or arch. The arch (*neural*) is formed of two *pedicles* and two *laminae*, supporting seven processes—viz., four *articular*, two *transverse*, and one *spinous*.

The bodies of the vertebrae are piled one upon the other, forming a strong pillar for the support of the cranium and trunk; the arches forming a hollow cylinder behind the bodies for protection of the spinal cord. The different vertebrae are connected together by means of the articular processes and the intervertebral fibro-cartilages; while the transverse and spinous processes serve as levers for the attachment of muscles which move the different parts of the spine. Lastly, each pair of vertebrae apertures exist through which the spinal nerves pass from the cord. Each of these constituent parts must now be separately examined.

The **Body** or **Centrum** is the largest part of a vertebra. Above and below, it is flattened; its upper and lower surfaces are rough for the attachment of the intervertebral fibrocartilages, and presents a rim around their circumference...."

Gray, Henry. *Anatomy of the Human Body*. Philadelphia: Running Press, 1974; p.34-35.

The Examiner also argues that the '679 Patent shows the bag in the intervertebral space and in the vertebral body. This argument again shows that the Examiner is confused about human anatomy. As can be seen in FIGS 4-7 of the '679 Patent, the container of the '679 Patent is placed between two vertebral bodies in the intervertebral space, not within a vertebral body

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itself as claimed in claims 22, 28-34 and 79. The '679 Patent does not disclose the use of a container in the vertebral bone and therefore does not render claims 22, 28-34 and 79 obvious.

The '536 Patent to Gibson does not disclose any container and therefore does not render claims 22, 28-34 and 79 obvious.

Because the use of a container to treat a vertebral body is patentably distinct from the use of a container to treat a degenerated intervertebral disc and because neither the '679 nor the '536 Patents disclose the use of a container to treat a vertebral body, Applicants submit that claims 22, 28-34 and 79 are allowable. In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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